

REMARKS/ARGUMENTS

By this Amendment, claims 21, 31, 43-45 and 47 are amended. Claims 21-47 are pending.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Entry of this Amendment is proper under 37 C.F.R. §1.116 because the Amendment: (a) places the application into condition for allowance (for reasons discussed herein), (b) does not raise any new issues requiring further search and/or consideration (because the Amendment is directed to subject matter previously considered during prosecution), (c) does not present any additional claims, and (d) places the application into better form for appeal, should an appeal be necessary. The Amendment was not previously made because the form of the Amendment was suggested by arguments first made in the Final Rejection. Applicants respectfully request entry of the Amendment.

Amendments to the Claims and Support for Amendment

Independent claims 21 and 45 have been amended to more clearly specify that the active substance comprised in the tablet is “*in a form of coated microcrystals or coated microgranules*”. The limitation was already present in previously presented versions of claim 21 and claim 45, which recited a tablet comprising “*coated microcrystals or microgranules of an active substance*”. Support for this amendment can also be found throughout the specification as originally filed (see, for example, page 1, lines 29-30, as well as all the Examples of the patent application). The language of the amended claims more clearly distinguishes the claimed tablet (and claimed process) from the prior art. In particular, the new language more specifically highlights the fact that a coating envelopes the active substance.

Claims 31, 43-45 and 47 have been amended to correct minor typographical errors and for improved clarity.

Rejections under 35 U.S.C. § 103

Claims 21-39 and 40-41 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hunter *et al.* (U.S. Pat. No. 6,391,337) in view of Schmitz *et al.* (U.S. Pat. No. 6,079,968), and Valentine (U.S. Pat. No. 4,684,534). Claims 31 and 42-47 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hunter *et al.* in view of Schmitz *et al.*

In the Final Rejection, the Examiner states that the Hunter *et al.* reference teaches pharmaceutical dosage forms for a rapidly disintegrating tablet, and processes for making this tablet. The Examiner further states that the tablets disclosed in Hunter *et al.* can comprise various saccharides, a lubricant, a disintegrant as well as other additives, such as flavorants, sweeteners, and coloring agents, and notes that these dosage forms are prepared by direct compression of a dry granulate. The Examiner concedes that the Hunter *et al.* patent does not explicitly teach methods of manufacturing tablets wherein the lubricant is entirely or mostly applied to the outer surface of the tablet, but cites the Schmitz *et al.* patent for its alleged disclosure of a device that sprays powdered lubricants onto punches and dies of a tablet press and that can be readily retrofitted into existing machinery. The Examiner also cites the Valentine patent, as a teaching reference, which states that lubricants having a particle size of 44 microns or less are known and desired within the art of manufacturing tablets.

The Examiner has taken the position that it would have been obvious to one skilled in the art, at the time the invention was made, to combine the teachings of Hunter *et al.* and Schmitz *et al.* to obtain the instantly claimed invention.

Applicants respectfully disagree, and for reasons set forth below, respectfully submit that the Examiner has failed to show that the prior art references teach or suggest all of the claim limitations, as required to support a *prima facie* case of obviousness.

In particular, Applicants respectfully point out that the Examiner seems to have overlooked the limitation (present in the claims as originally filed) which requires that the active substance comprised in the claimed tablet be “in the form of coated microcrystals or coated microgranules”. The Examples of the patent application describe, in particular, tablets comprising *coated* microcrystals of paracetamol (see Example 1), *coated* ibuprofen granules (see

Example 2), and *coated* aspirin granulate (see Example 3). In contrast, in the tablet taught by the Hunter *et al.* patent, the active substance, *i.e.* acetaminophen, is NOT coated. Although Hunter *et al.* contemplate coating of the tablet itself (see, for example, column 14, lines 29-65), the Hunter *et al.* patent does not disclose or suggest a compressible tablet comprising an active principle that is enveloped by a coating.

Applicants would also like to point out that the presence of a coating enveloping the active substance implies that, in the claimed tablet, the active substance is not in direct contact with the tableting excipients (*e.g.*, disintegrant agent, soluble agent, and lubricating agent). This feature further distinguishes the claimed tablet from the tablet described by Hunter *et al.* (be it modified or not using the teaching of Schmitz *et al.*), where acetaminophen, the active principle, is in direct contact with the excipients.

In light of the arguments put forward above, Applicants submit that Hunter *et al.*, taken alone or in combination with Schmitz *et al.*, and Valentine, does not teach or suggest all the limitations of the compressible tablet recited in independent claim 21, or of the process for making such a tablet as recited in independent claim 45, and therefore does not render obvious any claims of the instant application. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Application No. 09/914,544
Amendment of 2/5/08
In Response to Final Rejection of 11/5/07

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

February 5, 2008

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